

### Remarks

Claims 56, 58, 60, 64, 66-68, of the present application have been amended. Claims 52, 54, 59, 61-63, 65, and 69-73 have been cancelled. Claims 53, 55, 57, have been withdrawn. New claims 74-82 have been added. Support for the new claims can be found throughout the specification. More specifically, support for claim 74 can be found on pg. 3, Ins. 1-14 and pg. 9, Ins. 13-20 of the present specification. Support for claim 75 can be found on page 5, Ins. 1-18 of the present specification. Support for claims 76 and 77 can be found on page 9, Ins. 13-20 of the present specification. Support for claims 78 and 79 can be found on page 5, Ins. 15-17 of the present specification. Support for claims 80 and 81 can be found on page 5, Ins. 17-18 of the present specification. Support for claim 82 can be found in the paragraph bridging pages 8 and 9 of the present specification. Support for amended claim 56 can be found on page 9, Ins. 13-20 of the present specification.

The claims of the present invention contain the same subject matter as the claims presently allowed in Europe.

### 35 U.S.C. 103(a) Rejection

According to the Examiner, claims 52, 54, 56 and 59-73 were rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Bodmer et al in view of Shalaby et al '659. Applicants respectfully traverse the arguments.

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

Bodmer et al. do not teach or suggest all the claim limitations recited in the present claims. Bodmer et al. describe microparticles comprising polypeptides. The claims of the present invention recite polylactide polymers. Furthermore, there is no suggestion of motivation in Bodmer et al. for one of ordinary skill in the art to modify the teachings of Bodmer et al. to arrive at the present invention.

Shalaby et al. do not correct the deficiencies of the primary reference, Bodmer et al..  
Shalaby et al. teaches the use of charcoal for removing side products.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. *In re Vaeck*, 974 F.2d 488, 20 USPQ.2d 1438 (Fed. Cir. 1991). Shalaby et al. do not teach or suggest the removal of the catalyst, tin as described in the present invention. At the time of Shalaby et al., a person of ordinary skill would not have known that charcoal could be used for removing the catalyst. At that time, charcoal was added to remove the colored impurities. At that time, nothing in Shalaby et al. suggested that the catalyst could be removed using charcoal. Therefore, the reasonable expectation of success of removing the catalyst, tin, using charcoal is not found in Shalaby et al. Applicants respectfully request that the rejection be withdrawn from consideration.

Entry of this Response is respectfully requested.

Respectfully submitted,

Novartis  
Corporate Intellectual Property  
One Health Plaza, Building 104  
East Hanover, NJ 07936-1080  
(862) 778-7852



Oona A. Jackson  
Attorney for Applicant  
Reg. No. 48,152

Date: May 24, 2005